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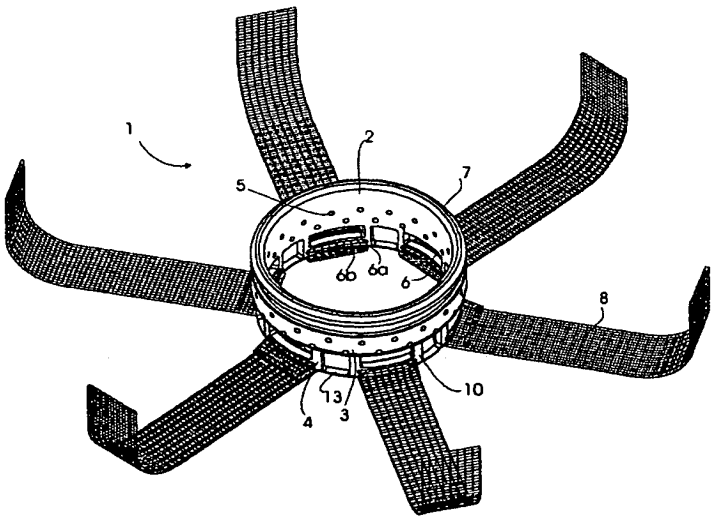

(57) Abstract: An implant (1) for implantation into an animal or a human body, comprising an axial interior section (3) for fixation inside the body and an axial exterior section (2), extending outwards from the body for mounting of a device which can be detachably connected to the body via the ring. The interior section (3) and the exterior section (2) are connected to each other by means of at least one connecting piece (4) with at least one transverse opening (6). Through the transverse openings (6), tissue can be formed for fastening of the implant (1). The fastening can be additionally secured by placing a number of anchoring means (8) in the transverse openings (6).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Implant

The invention relates to an implant for implantation into an animal or a human body, comprising an axial inner portion for fixation inside the body and an axial outer portion extending outward from the body and serving for mounting of a device which can be detachably connected to the body via the ring.

There are numerous medical conditions in the gastrointestinal canal and in the urinary system which require a surgical intervention with temporary or permanent performance of a stoma. After such intervention, excrements or urine is traditionally collected in a stoma pouch, adhering to the skin and surrounding the stoma.

The demands for a tight adhesive surface are heavy. If liquid secretion penetrates the adhesive surface, this surface will loosen more or less, resulting in leakage from the pouch and release of unpleasant smell.

Consequently, there is a demand for alternatives to traditional combinations of adhesive face plates and stoma pouches.

US patent No. 4,265,244, No. 4,532,761 and No. 5,242,415 disclose partially biocompatible implants, forming a leakproof fastening device for the stoma pouch after ostomy surgery.

The implants known from the above patent specifications all comprise a flange portion to form a fixed anchor for the implant in the body. The flange can be wholly or partly covered with a biocompatible mesh, which enables and encourages tissue repair and ingrowth of the implant.

To enable implantation of a device with such a flange, it is necessary to make a relatively large incision in the abdominal wall for insertion of the implant. The construction of such

implants being relatively large and rigid, the surgically treated patient frequently senses the presence of the implant which causes discomfort.

GB 2 019 219 discloses yet another implant with a rigid flange, extending horisontally from the conical body. The flange is perforated by a number of holes to facilitate growth therethrough of fresh tissue, thereby improving tissue bonding between implant and body. This construction is large in width as well and consequently requires a large surgical incision, and the presence of the flange causes considerable discomfort for the patient.

Numerous of the above disadvantages have been rectified by the implant known from international patent application PCT/EP98/04029, where the inventors of the present invention are co-inventors.

The object of the invention is to provide an implant of the kind mentioned in the opening paragraph, which requires a smaller surgical incision than known so far with no direct mucocutaneous contact and which can be safely and securely fixated to an underlying skin layer or into a muscle without being fitted with a flange.

A second object of the invention is to provide an implant, which is not sensed by the patient after implantation, and which can be detachably attached to and disconnected devices, such as e.g. caps or pouches, thereby giving the surgically treated patient an unprecedented comfort.

A third object of the invention is to provide an implant, causing an unprecedented minimum of allergic and inflammatory reaction.

A fourth object of the invention is to provide an implant with an easily adjustable axial extension to fit heavy as well as thin patients.

The novel and unique features, whereby this is achieved according to the invention, is the fact that in principle the implant is tubular, and that the interior section consists of an anchoring ring and a continuous connecting piece between this and the exterior section, designed with at least one throughgoing transverse opening.

When the connecting piece of the interior section consists of one rod, extending between the anchoring ring and the exterior section, one single opening is produced between them, and when the connecting piece of the interior section consists of more than one rod, extending between the anchoring ring and the exterior section, the connecting piece is constructed as an open grid. Particularly appropriately, the rods may be evenly distributed along the anchoring ring and the exterior section.

When in this way at least one throughgoing transverse opening is produced between the interior section and the exterior section of the ring, new healed tissue and vascular system can naturally be formed through such transverse opening in such a way that in the course of very short time, a natural blood supplied biological fastening of the implant will be established, in the course of implantation said implant having been at least partly embedded into the body.

The total quantity of non-biological material, embedded into the body and in direct contact with body tissue, will be considerably smaller than known so far. The risk and the probability of allergic and inflammatory reactions have therefore been reduced significantly in a simple way and are far smaller than previously established.

A part of the axial extension of the at least one throughgoing transverse opening may in some cases advantageously be left outside the body, allowing ingrowth through the at least one transverse opening to occur partly on the outside and over cutis. In this way, only an insignificant part of the implant is implanted, and at the same time strong fixation is secured.

At the end facing the connection piece, the exterior section of the implant can advantageously be fitted with a ring-shaped section with a number of evenly distributed suturing perforations.

By securing the implant solidly in a skin layer by suture through the suturing perforations in the first phase after surgery, the implant can be fixated at the required site in a simple manner. Thus, when the implant has been made resistant to compressive and tensile stress in this way, optimal conditions have been procured for the subsequent tissue healing phase, where fresh tissue grows through the transverse openings.

By e.g. producing several rings of suturing perforations, a possibility of leaving a larger or smaller part of the implant outside the body is created. This way, suturing can be performed either in cutis or in subcutis or in both skin layers, depending on how much of the exterior section of the implant is desired to remain outside the body.

In a second embodiment of the invention, the end opposite the exterior section of at least one of the rods of the connecting piece tapers.

When each rod tapers towards the free end, the implant can slidably be inserted readilly through the skin around e.g. a stoma using a very simple implantation method, and

subsequently it can slidably be inserted further down towards an underlying muscle or fascia.

In an alternative implantation method, a number of insertion apertures corresponding to the number of rods can be made in the abdominal wall, serving to accommodate the rods.

Marking of insertion apertures can be made either by simple sketching and making them one at a time, or by simultaneous marking of all apertures by a purpose-designed cutting former plate for making an aperature for each rod at one time. In this way, the depths and widths of all apertures are ensured in a simple way for accurate accommodation of the rods to the necessary extent.

At least one throughgoing hole can be made at the free end of each rod, said hole being arranged for accommodating at least part of the anchoring ring. When an anchoring ring of a material similar to e.g. the implant is led through the holes of the rods, fastening between implant and body will become exceptionally strong.

Consequently, the implant becomes immediately resistant to compressive and tensile stress, the anchoring ring locking the implant in the tissue layer, where placement of the rods is chosen and through which the anchoring ring is forced.

When the ring is slidably inserted through the holes in the rod, the ring, the interior section and the rods together form transverse openings, corresponding to the previously mentioned transverse openings, in which subsequent appropriate attachment of a number of anchoring means is enabled. Similarly, a space between anchoring means and transverse openings can, as described above, be provided by means of antimicrobial impregnated threads.

This embodiment of the implant provides an extremely strong fastening in the tissue, and the implantation only requires a very small surgical intervention. If removal of the implant may be required at a later stage, this can be done in a simple way by removal of the ring fixating the implant first and subsequent removal of tissue formation at the suturing perforations, if any, whereupon the implant can be pulled out in a simple manner.

For patients with e.g. particularly pronounced obesity, the axial extension of the implant must be sufficiently long for the anchoring ring to bear against a biological platform such as a muscle. The above mentioned embodiment is particularly applicable for such patients, as the rods in such cases may advantageously be designed with additional length.

In as much as different patients have different thicknesses of skin and fat layers as well as a more or less deep-set musculature, the axial extension of the implant is adjustable in the alternative embodiments of the implant according to the invention. Consequently, the axial extension is advantageously adaptable to the actual individual need, required in the immediate situation.

In the above described embodiments of the implant according to the invention, the connecting piece is a straight rod, connecting the anchoring ring and the exterior section in principle at right angles.

In an alternative embodiment, the connecting piece can consist of at least one rod, extending in waveform between the anchoring ring and the exterior section.

For a particularly corpulent or adipose patient, the at least one rod can advantageously be U-shaped, V-shaped or S-shaped, in principle following the curve of the ring.

After evaluation of the condition of the individual patient and estimation of a necessary axial extension of the implant, the exterior and interior sections of the implant are pressed against each other to reduce the axial extension of the implant, or the exterior and interior sections of the implant are pulled in opposite directions to increase the axial extension of the implant, causing the axial extension of the implant to subsequently match the actual patient and the immediate situation accurately.

Other geometrical configurations for the connecting piece, e.g. zigzag configurations of linked U's, V's or S's, or e.g. sine or cosine curves, are also included within the scope of this invention.

In a second alternative embodiment, which is particularly advantageous for e.g. obese patients, the at least one rod extends between the anchoring ring and the exterior section along an in principle helical shape.

Such a construction provides high flexibility of the axial extension of the implant, and larger and smaller extensions are obtainable in a manner similar to that of the above mentioned embodiment, where V-shaped rods form the connecting piece, namely by pulling the interior and exterior sections in opposite directions or by pressing the interior and exterior sections together, respectively. By giving the connecting piece a helical shape with several threads, the axial extension can be much increased.

Production of threads in such a helix is particularly simple by merely cutting up a connecting piece, which is a connecting part between interior and exterior sections, until the required number of threads has been produced.

A particularly solid construction is achieved, when the connecting piece consists of several parallel helixes, where the space between the threads produces one or several openings, forming the previously described transverse openings.

By giving the connecting part a helical shape, the flexibility of the axial extension is high, with no requirement for implantation of additional non-biological material for providing a means for fixation of the implant to a biological platform.

The width or the thickness of the rod is variable, depending on the requirements for stability and flexibility of a device.

By turning the anchoring ring and the exterior section of the implant on their common axis in opposite directions, it is possible to increase or reduce the diameter of part of the connecting piece compared to the diameter of the exterior section and the anchoring ring.

To additionally ensure fastening in the body, anchoring means can be affixed to the anchoring ring with mutual angle spacing. The anchoring means extend outwards to a free end and can advantageously consist of a biocompatible, flexible material.

By way of example, the anchoring means can be porous, flexible, elongated textile meshes, produced in a well-known biocompatible material.

Examples of such applicable polymers are DACRON, PROLENE, VICRYL, GORE-TEX or SURGIPRO.

By producing the anchoring means of textiles, they become so flexible that they advantageously can be directed in any

fixation direction. The length of the anchoring means is adjustable after the individual anatomical conditions, and their ductility and flexibility enable fixation of the anchoring means to e.g. more or less deep-set muscularis or fascia and at different angles and spaces from the interior section.

Application of anchoring means for fixation of the implant will contribute to advantageously reduce the greatest required axial extension of the ring, and to advantageously reduce the quantity of implanted non-biological material correspondingly.

To prevent that the anchoring means act as wicks for bacteria-rich secretion from the excrements, each anchoring means can be spaced apart from the relevant transverse opening by means of threads of a biocompatible material.

By impregnating the threads with an anti-microbial preparation, e.g. $AgNO_3$ or an antibiotic, the risk of post-operative abdominal infection is very small or has been entirely eliminated.

In case of patients with e.g. obesity, hernia, or cicatricial tissue formation, or patients developing such post-operative or similar discomforts at a later stage, it may be required at least temporarily to enlarge the axial extension of the exterior section to permit and/or facilitate mounting of the device which will be attached to the exterior section.

Similarly, for a period after an operation where an implant has been implanted in a patient, oedema and swelling in the operated tissue may occur which will hinder correct attachment of e.g. a stoma pouch on the implant.

Such disadvantages can be eliminated in a simple way, when the implant comprises an extension ring which in use can be

mounted in such a way that the part of the axial extension of the implant comprising the exterior section can be advantageously increased. The extension ring has a connecting portion which can be detachably connected to the exterior section, and facing in the opposite direction of the connecting portion, one free end part which can be mounted with a detachable device desired connected to the body.

By fitting the connecting portion of the extension ring with a number of catches, in mounted state of the connecting portion detachably locking under a flange on the exterior section, the extension ring can in a simple way be attached to either the implant or to an additional extension ring.

Optimum assembly of the extension ring is ensured when the edge of the connecting portion facing the exterior section of the implant in mounted state is designed with a circumferential groove with a bottom designed to bear closely against the adjacent edge of the flange of the exterior section.

In addition, by interposing an O-ring between the bottom of the circumferential groove of the connecting portion and the adjacent edge of the flange of the exterior section, completely tight sealing between the extension ring and the implant is secured.

The inside diameter of the extension ring corresponds to the inside diameter of the implant, and when mounted on the implant, an entirely plane transition between the extension ring and the implant is provided.

To prevent accidental pulling of the extension ring off the implant, e.g. when a device is attached or removed, the extension ring and the implant can also be interlocked by a locking ring passing closely over the extension ring. Such a

locking is most expediently achieved by designing the locking ring with at least one radial interior portion, equivalent to or slightly greater in diameter than the space between the exterior of two of the diametrically opposite catches of the connecting portion.

When the radial interior portion is shaped as a circumferential groove for accommodating the catches of the connecting portion, the joint between the implant and the extension ring can be fixated and sealed in a simple way.

The implant with belonging parts can advantageously be manufactured of a material which is known not to produce allergic reactions and which is approved by the health authorities for application in implantations.

A preferably rigid implant can be manufactured of titanium or possibly of a titanium alloy.

A preferably bendable and flexible implant can be manufactured of a biocompatible synthetic or biosynthetic polymer. As an example, polyurethane or polyurethancopolymer can be mentioned.

Furthermore, at least part of the implant can advantageously be covered with such biocompatible polymer.

The implant according to the invention can advantageously be applied in enterostomies. Enterostomies are accomplished by exteriorizing the intestine through an opening in the abdominal wall. The intestinal opening is sutured to the skin in the course of the process in such a way that skin and intestine will subsequently grow together. The implant can be implanted prior to performance of a stoma or after conclusion of such, thus surrounding the stoma in a distance to prevent direct mucocutaneous contact.

Alternatively, the implant can be implanted and sutured to the intestine as well as to epidermis via the suturing perforations.

The implant according to the invention can be designed with any combination of diameter and axial extension and is consequently applicable together with any shape, size or type of performed ostomy, e.g. colostomy, ileostomy, urostomy, pneumostomy or tracheotomy.

Alternatively, the implant can advantageously be applied in cases where a device is required to be attached to the body. Such a device in form of a stoma pouch is known from the applicants' Danish patent application PA 2000 00025.

As an additional example can be mentioned a very thin, flexible implant, relatively great in diameter. Such an implant can be implanted into a bald top of the head, and a wig designed to be detachably linked to the implant can thus be attached to and removed from the implant in a simple way, thus ensuring wig wearers that their wigs are firmly fixated under all circumstances and external influences.

The invention is described in more detail below, describing exclusively examples of embodiments with reference to the drawing, in which

Fig. 1 shows, in perspective, a first embodiment of an implant with anchoring means according the invention,

Fig. 2 shows the same, but with anchoring means spaced apart from the implant by means of threads,

Fig. 3 shows, in perspective, an exploded view of a second embodiment of an implant according to the invention,

Fig. 4 shows, in perspective, a third embodiment of an implant according to the invention,

Fig. 5 shows, in perspective, a fourth embodiment of an implant according to the invention,

Fig. 6 shows, in perspective, the fourth embodiment, but with two threads on the connecting piece,

Fig. 7 shows, in perspective, the fourth embodiment, but with two rods on the connecting piece,

Fig. 8 shows, in perspective and partly sectional, an exploded view of an implant with an extension ring, an O-ring and a locking ring,

Fig. 9 shows, in perspective and partly sectional, the extension ring in mounted state on an implant, where it is locked by a locking ring, and

Fig. 9a shows on an enlarged scale a feature of fig. 9.

The implant shown in fig. 1 and 2 is in its entirety designated with reference number 1.

Figs. 1 and 2 show an implant 1 with an axial exterior section 2, an axial interior section 3, consisting of an anchoring ring 13 and a continuous connecting piece 4 between the anchoring ring 13 and the exterior section 2. In the part of the exterior section 2 facing the connecting piece 4, one or several rings of suturing perforations 5 are designed, and the anchoring ring 13 and the exterior section 2 are in the shown example connected by a connecting piece with twelve rods 10, forming twelve transverse openings 6, that in the embodiment of figs. 1 and 2 as an example each are divided into two fractional transverse openings 6a and 6b. In figs. 1 and 2 the

implant is as an example shown with six transverse openings 6, but this embodiment of the implant may contain any number of transverse openings 6 within the scope of the invention.

The exterior section 2 is designed with a flange 7, to which by way of example a stoma pouch or a locking device (not shown) can be attached. Anchoring means 8 are mounted in the fractional transverse openings 6b and in the illustration example all six fractional transverse openings 6b are fitted with anchoring means 8. The anchoring means 8 are preferably manufactured of a porous biocompatible polymer and are flexible. The anchoring means 8 are here shown with equivalent lengths, but can within the scope of the invention be longer or shorter.

In fig. 2, the anchoring means 8 are distanced from the transverse openings 6b by means of threads 9, which are preferably impregnated with an antimicrobial preparation.

Fig. 3. shows a second embodiment of the implant according to the invention. The exterior section 2 with the flange 7 has in the shown example only one ring of suturing perforations 5 and along the part of the circumference of the exterior section 2 facing in the opposite direction to the flange 7, twelve evenly distributed, elongated, axially extending rods 10 are mounted, forming the connecting piece 4. Each rod 10 tapers towards the free end 11. In the free end 11 of each rod 10 at least one hole 12 is made, through which an anchoring ring 13 can be inserted.

In the transverse openings 6, which are produced by inserting the anchoring ring 13 into the holes 12 of the rods 10, anchoring means 8 (not shown) can be placed in a similar manner as shown in figs. 1 or 2.

The implants shown in figures 1, 2 and 3 are mainly ring-shaped with a relatively small axial extension.

The embodiments of the implant according to the invention shown in figs. 4-9 are alternative embodiments of the shown implant of figs. 1 and 2. However, the embodiments of figs. 4-9 are all adjustable to a larger axial extension, and identical parts are referred to with identical reference numbers.

The embodiment shown in fig. 4 has a connecting piece 4, as an example consisting of six rods 10, forming six transverse openings 6. The rods 10 are in the shown example of embodiment bent into a V-shape, but may within the scope of the invention be given any shape. As an example can be mentioned an S-shape, a U-shape or coherent combinations of such shapes, e.g. a zigzag-shape. In addition, the bent rod 10 is bent mainly to follow the tubular shape of the implant. By pulling the exterior section 2 away from the anchoring ring 13, the angle between the legs of the V is enlarged, and the axial extension of the implant can be increased to a maximum where the space between the interior section and the exterior section corresponds to the total of the length of the two legs of the V. Six anchoring means 8 are attached to six evenly distributed fractional transverse openings 6b.

In the embodiment of fig. 5, the interior section 3 and the exterior section 2 are connected by the connecting piece 4, consisting of one helical rod 10. The connecting piece 4 is here shown as a narrow thread, but the invention is not limited to narrow threads in as much as wide threads may be more suitable for some purposes where the demands for a highly stable construction with great axial extension are heavy.

The embodiment of fig. 6 corresponds to the embodiment shown in fig. 5, but the helical connecting piece 4 has in this case a rod 10 with two threads 10' and 10''.

The embodiment shown in fig. 7 has a connecting piece 4, consisting of two rods 10 each in the shown example with a helix with a thread 14 and a thread 15 respectively, extending from two spots on the anchoring ring 13, diametrically opposite one another. This construction is very stable and provides a well-defined passage for a body part, e.g. a vessel or part of an intestine, to be exteriorized through the implant 1. As in the above shown embodiments, fresh healed tissue and vascular system will be formed in a natural way through the transverse openings 6, enabling establishment of a natural blood supplied biological fastening of the implant in the course of very short time.

Fig. 8. shows an implant 1, similar to the implant shown in fig. 5, an extension ring 16, an O-ring 17 and a locking ring 18.

The extension ring 16 has a connecting portion 19 with catches 20 and a flange 7, identical to the flange 7 of the implant 1 and placed opposite the connecting portion 19.

The coupling of the extension ring 16 to the implant 1 is shown in more detail in fig. 9 and fig. 9a. In fig. 9 the extension ring 16 is attached to the implant 1 and locked by the locking ring 18.

Detail figure 9a shows sectional and in more detail the coupling of the implant 1 to the extension ring 16 and the locking by means of the locking ring 18.

The extension ring 16 is shown in mounted state on the implant 1, where the catches 20 of the extension ring lock under a flange 7 on the exterior section 2 of the implant 1.

The edge of the connecting portion 19, in mounted state facing the exterior section 2 of the implant, has a circumferential groove 21, the bottom of which bears closely against the adjacent edge of the flange 7 of the exterior section 2.

To ensure tight sealing of the extension ring 16 to the implant 1, an O-ring 17 has been affixed between the bottom of the circumferential groove 21 of the connecting portion 19 and the adjacent edge of the flange 7 of the exterior section 2.

The locking ring 18 has a radial interior portion 23 in diameter corresponding to the space between the exterior sections 24 of diametrically opposite catches 20 on the connecting portion 19 of the extension ring 16. The radial portion 23 of the locking ring 18 has a circumferential groove 22, which is slidably inserted over the catches 20 of the extension ring 16. In mounted state, the locking ring presses the extension ring 16 firmly and tightly sealing against the implant 1.

Additional extension rings can be mounted above one another until appropriate necessary extension has been obtained.

Example 1

Various combinations of the implant have been tested, i.e. with and without biocompatible polymer cover, and implants of various materials have been applied, all of which are within the scope of this invention.

Approval for the tests has been procured and granted by the Dyreforsøgstilsynet (Danish Animal Experiment Authorities), Slotsholmsgade 12, st., 1216 Copenhagen K, Denmark, to prepare for implantation into 10 pigs per year under general anaesthesia.

Specially bred Göttingen test pigs were observed for up to 2 months in stalls prior to surgery in consideration of existing rules for animal experiments and after conclusion of colostomy and intracutaneous implantation of the implant, the pigs were treated with analgesics, if necessary.

The animals were killed after a period of up to 31 days, and the implant and the adjacent tissue were examined histologically at Biomedical Laboratory, Odense University Hospital, Denmark.

The results are compiled in the below table, of which appears

- that none of the pigs showed signs of allergic reaction
- a very high degree of ingrowth through the transverse openings as well as through the meshes was observed, resulting in a very high degree of intradermal fixation, providing a means for a detachable link to the body via the ring.

The histological studies were performed on colon inclusive of a circular piece of the skin surrounding the stoma. The results are shown in the below table.

	Implant	Number of implantation days	Rejection	Fibrotic	Ingrowth/ Attachment	Infection	Eosino-philocytes	Cause of destruction
1	Implant (covered with GORE-TEX, and PROLENE meshes applied)	18	0	+	0	0	0	Intestinal stenosis
2	Implant	28	0	+	0	0	0	Poor general condition
3	Implant (covered with GORE-TEX, and PROLENE meshes applied)	7	0	+	0	0	0	Intestinal stenosis
4	Implant	31	0	+	0	0	0	Not registrered
5	No implant	8	Necrosis of stoma	+	Not registrered	(+)	0	Poor general condition/hernia
6	No implant	30	Necrosis of stoma	+	Not registrered	0	0	Intestinal stenosis
7	Implant (covered with GORE-TEX, and GORE-TEX meshes applied)	30	Stenosis	+	0	0	0	Stenosis/ no appetite
8	Implant	7		+	0	Fibrinoid peritonitis	0	No appetite/ poor general condition
9	Implant (skin-skin)	14	0	+	Ingrowth of cutis through transverse openings of implant	0	0	Not registrered

However, pigs are less suitable for this type of experiment, having a relatively high tendency towards developing stenosis and fibrosis.

Example 2: Performance of human sigmoidestomy

Approach is created through umbiculus, the sigmoideum snare is released by incising fascia fusion layer of Toldt. A marked access site is prepared on the front abdominal wall, and the implant which has been kept in gentamycin solution is implanted and secured to the body by fixating the interior section of the implant to fascia and by tunnelling the PROLENE meshes and fixating them to fascia. New skin is adapted into the implant, which is secured by suture to the skin through the sututing perforations. This ensures that the implant is suitably fixated and well-placed. In the centre of the implant a hole is formed in the abdominal wall. Through this hole sigmoid is exteriorized and left unfashioned and unfixated to begin with. After 12 days the intestine is cut off to a suitable level, and a pouch designed for attachment to the implant is mounted. The condition of the patient is good.

Claims

1. An implant (1) for implantation into an animal or a human body, comprising an axial interior section (3) for fixation inside the body and an axial exterior section (2), extending outwards from the body and serving for mounting of a device which can be detachably connected to the body via the ring, **characterised** in that the implant is mainly tubular, and that the interior section (3) comprises an anchoring ring (13) and one continuous connecting piece (4) between the anchoring ring (13) and the exterior section (2), fitted with at least one throughgoing transverse opening (6).

2. An implant (1) according to claim 1, **characterised** by the connecting piece (4) consisting of at least one rod (10), extending between the anchoring ring (13) and the exterior section (2).

3. An implant (1) according to claim 1, **characterised** by the connecting piece (4) consisting of a number of rods (10), extending between the anchoring ring (13) and the exterior section (2), and in mounted state forming an open grid.

4. An implant (1) according to claim 3, **characterised** by tapering of the end of at least one of the rods (10) facing opposite the exterior section of the connecting piece (4), and by a throughgoing hole (11) in each rod (10), designed for accommodating at least part of the anchoring ring (13).

5. An implant (1) according to claim 1, **characterised** by the connecting piece (4) consisting of at least one rod (10), extending in waveform between the anchoring ring (13) and the exterior section (2).

6. An implant (1) according to claim 5, **characterised** by the shape of the at least one rod (10) being a U, a V or an S.

7. An implant (1) according to claim 1, **characterised** by the connecting piece (4) consisting of at least one rod (10), that along mainly a helix is extending between the anchoring ring (13) and the exterior section (2).

8. An implant (1) according to any of claims 1 - 7, **characterised** by the implant comprising a number of elongated anchoring means (8) affixed to the anchoring ring (13) with mutual angle spacing and extending from the anchoring ring to a free end, and the anchoring means (8) consisting of a biocompatible, flexible material.

9. An implant (1) according to claim 8, **characterised** by the part of each anchoring means (8) closest to the anchoring ring (13) consisting of at least one thread (9), fixed to the anchoring ring (13) and extending mainly in the longitudinal direction of the anchoring means (8), and the at least one thread (9) consisting of a biocompatible material.

10. An implant (1) according to claim 9, **characterised** by at least one thread (9) of each anchoring means (8) being impregnated with an antimicrobial preparation.

11. An implant (1) according to claim 10, **characterised** by the antimicrobial preparation being $AgNO_3$ or an antibiotic.

12. An implant (1) according to any of claims 1 - 11, **characterised** by the implant (1) comprising an extension ring (16) with a connecting portion (19) for detachably connecting the extension ring (16) to the exterior section (2), and one free end part facing opposite the connecting portion (19) to fit a detachable device for connection to the body.

13. The implant according to claim 12, **characterised** by the connecting portion (19) of the extension ring (16) being designed with a number of catches (20), in mounted state of the connecting portion (19) locking under a flange (7) on the exterior section (2).

14. An implant (1) according to claim 12 or 13, **characterised** by the edge facing the exterior section (2) of the implant (1) in the connecting portion (19) in mounted state being designed with a circumferential groove (21) with a bottom designed to bear closely against the adjacent edge of the flange (7) of the exterior section.

15. An implant (1) according to claim 14, **characterised** by the implant (1) comprising an O-ring (17), inserted between the bottom of the circumferential groove (21) of the connecting portion (19) and the adjacent edge of the flange (7) of exterior section.

16. An implant (1) according to any of claims 1 - 15, **characterised** by the implant (1) comprising a locking ring (18) with at least one radial interior portion (23), equivalent to or just a little greater in diameter than the space between the exterior sides of two diametrically opposite catches of the connecting portion.

17. An implant (1) according to claim 16, **characterised** by the said radial interior portion of the locking ring (18) being designed as a circumferential groove (22).

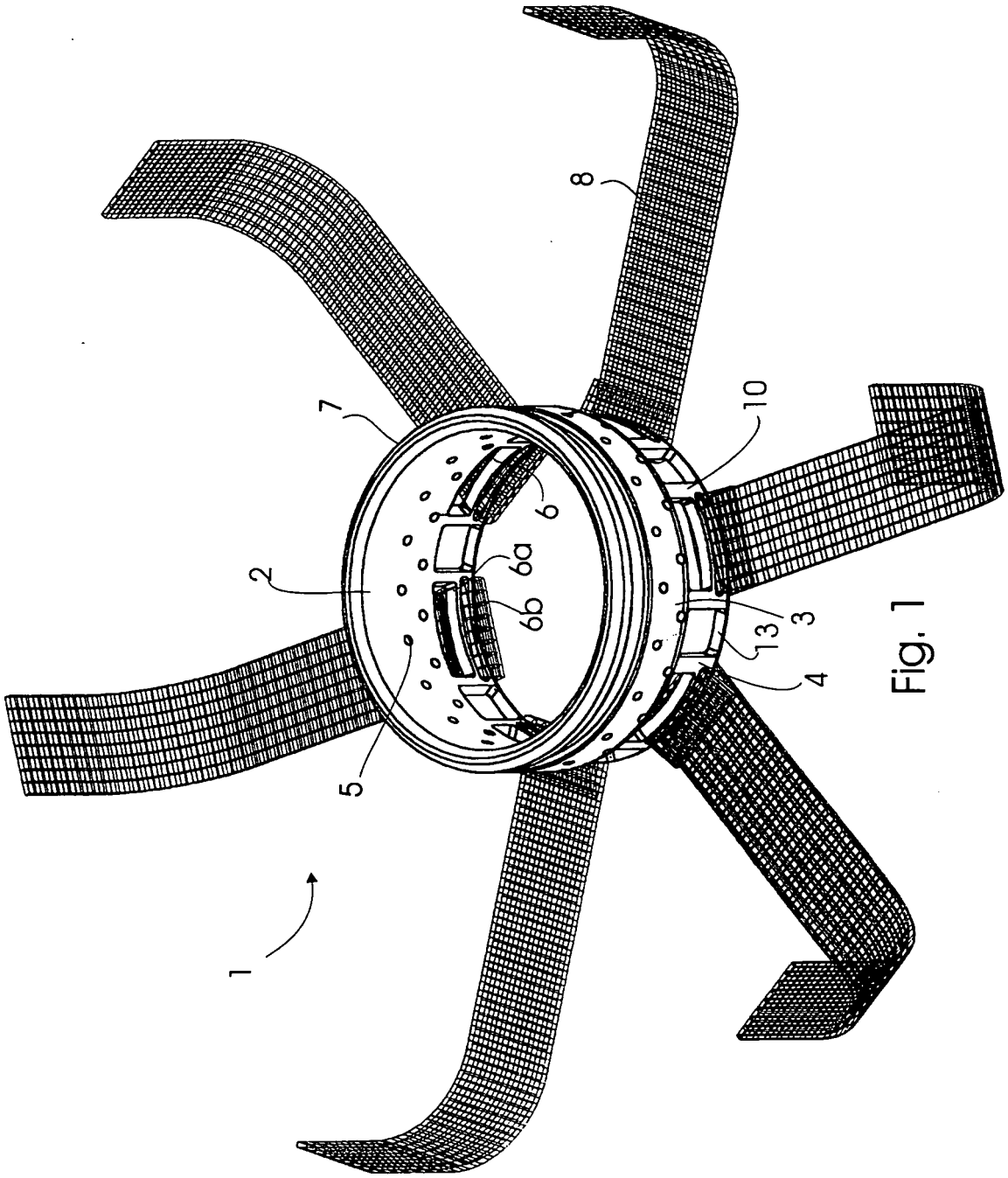

Fig. 1

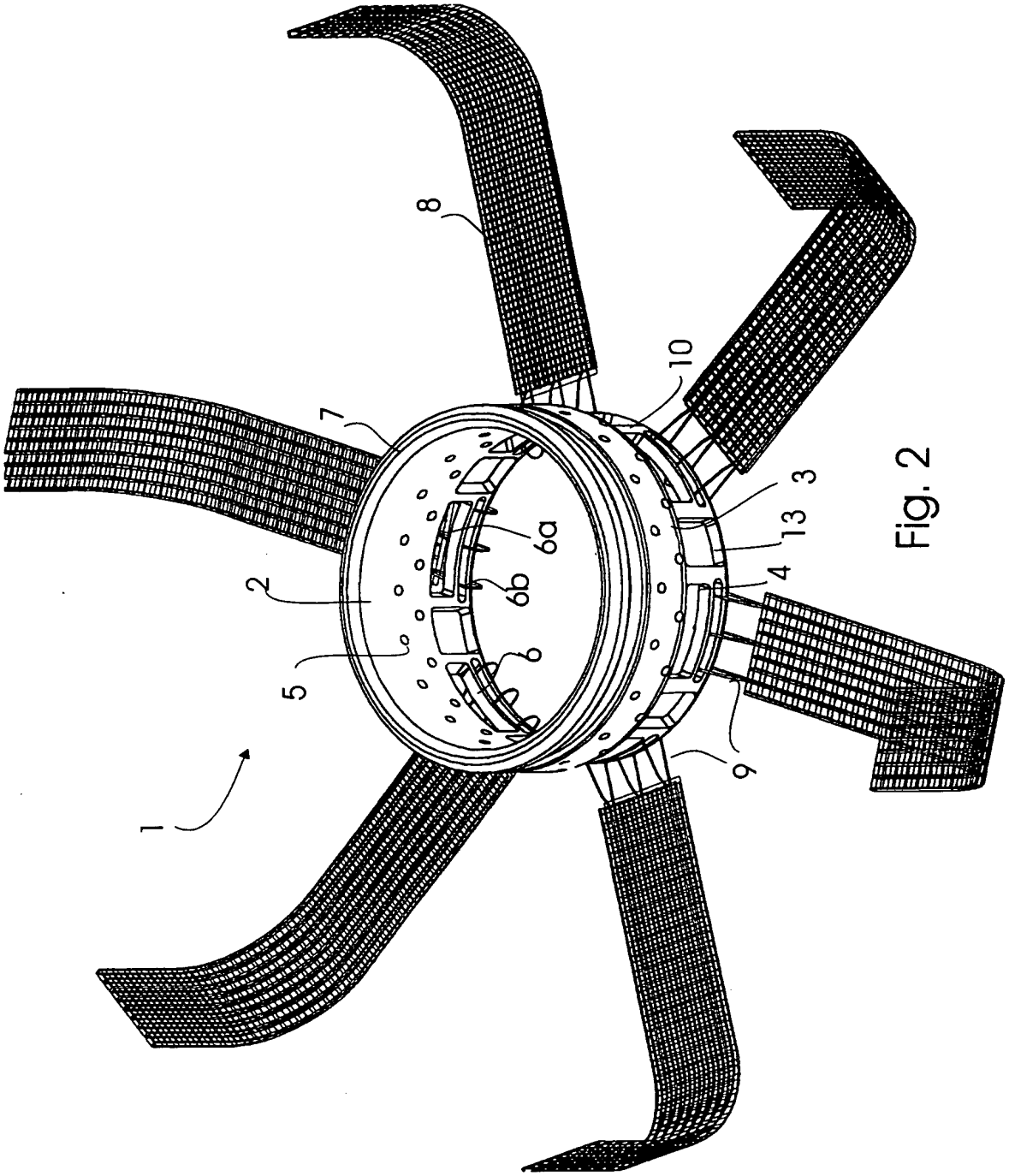

Fig. 2

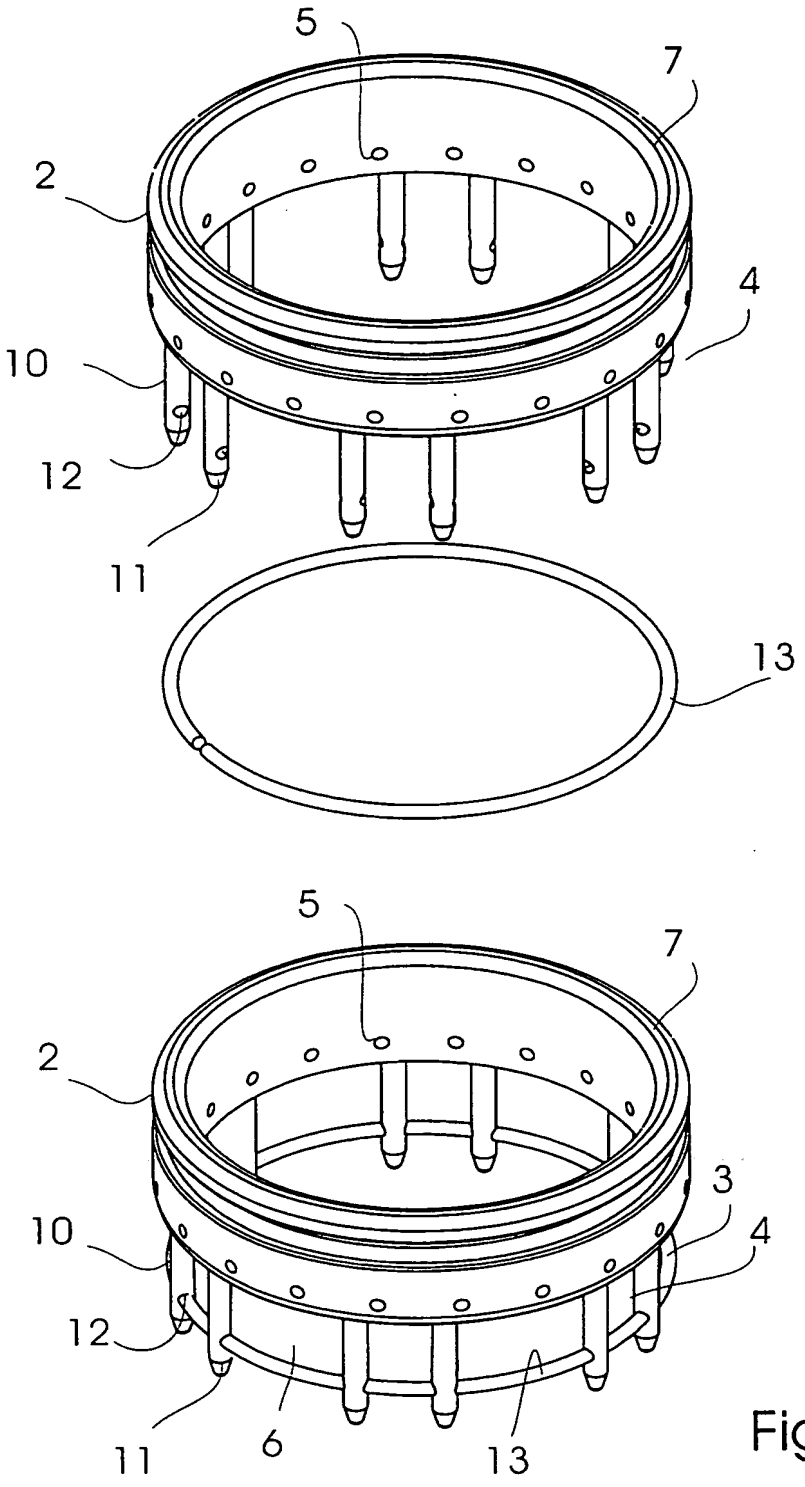

Fig.3

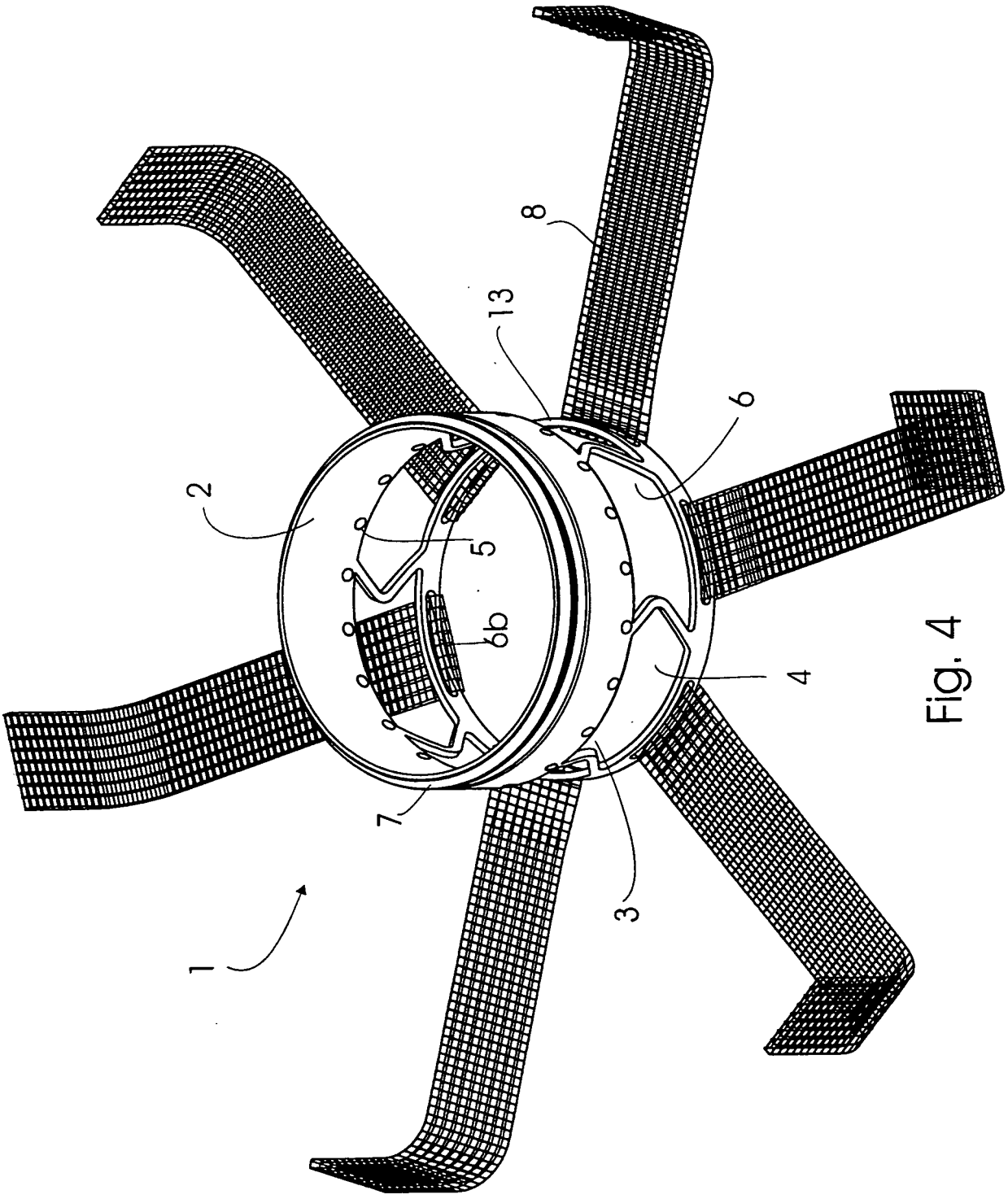

Fig. 4

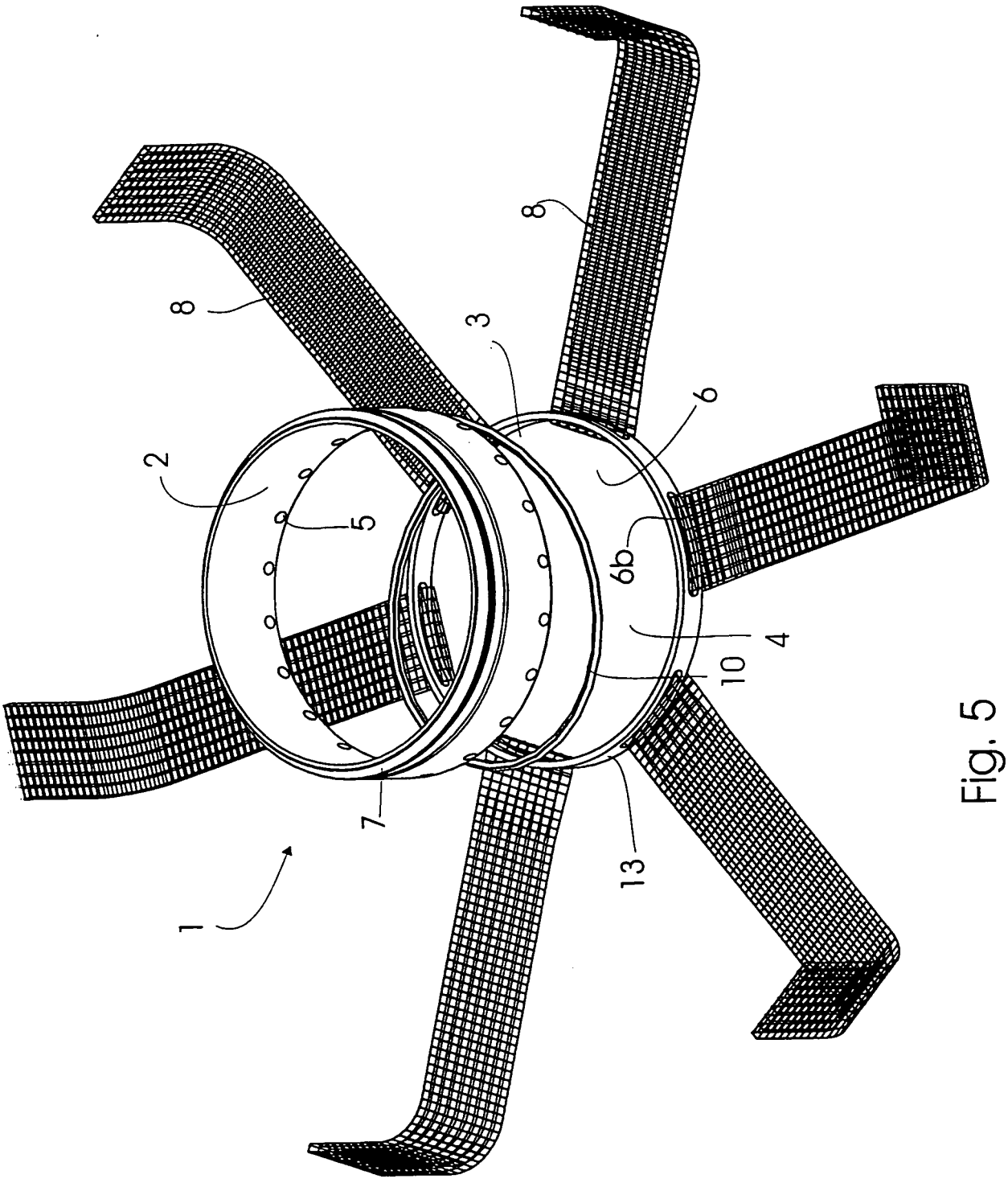

Fig. 5

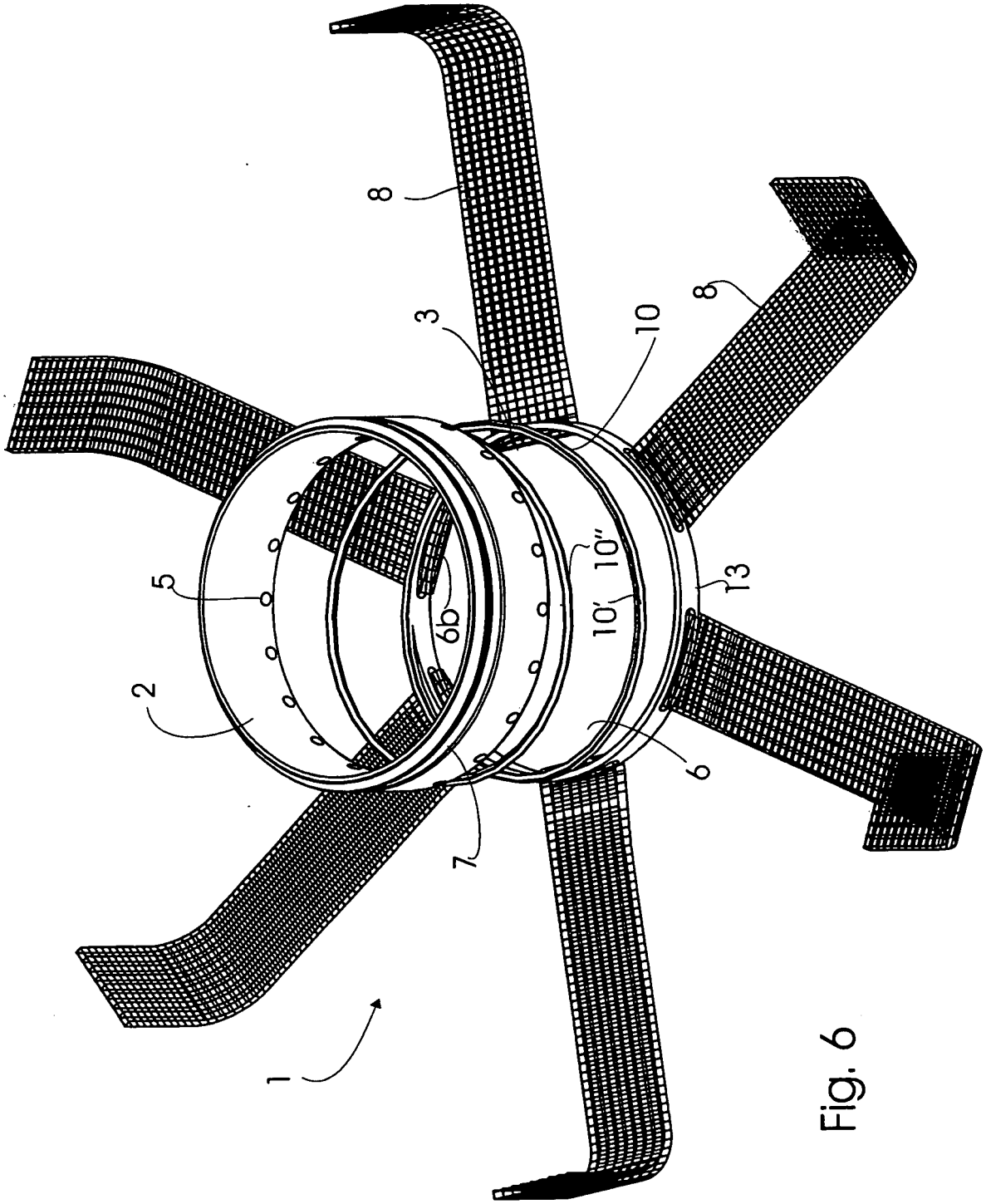

Fig. 6

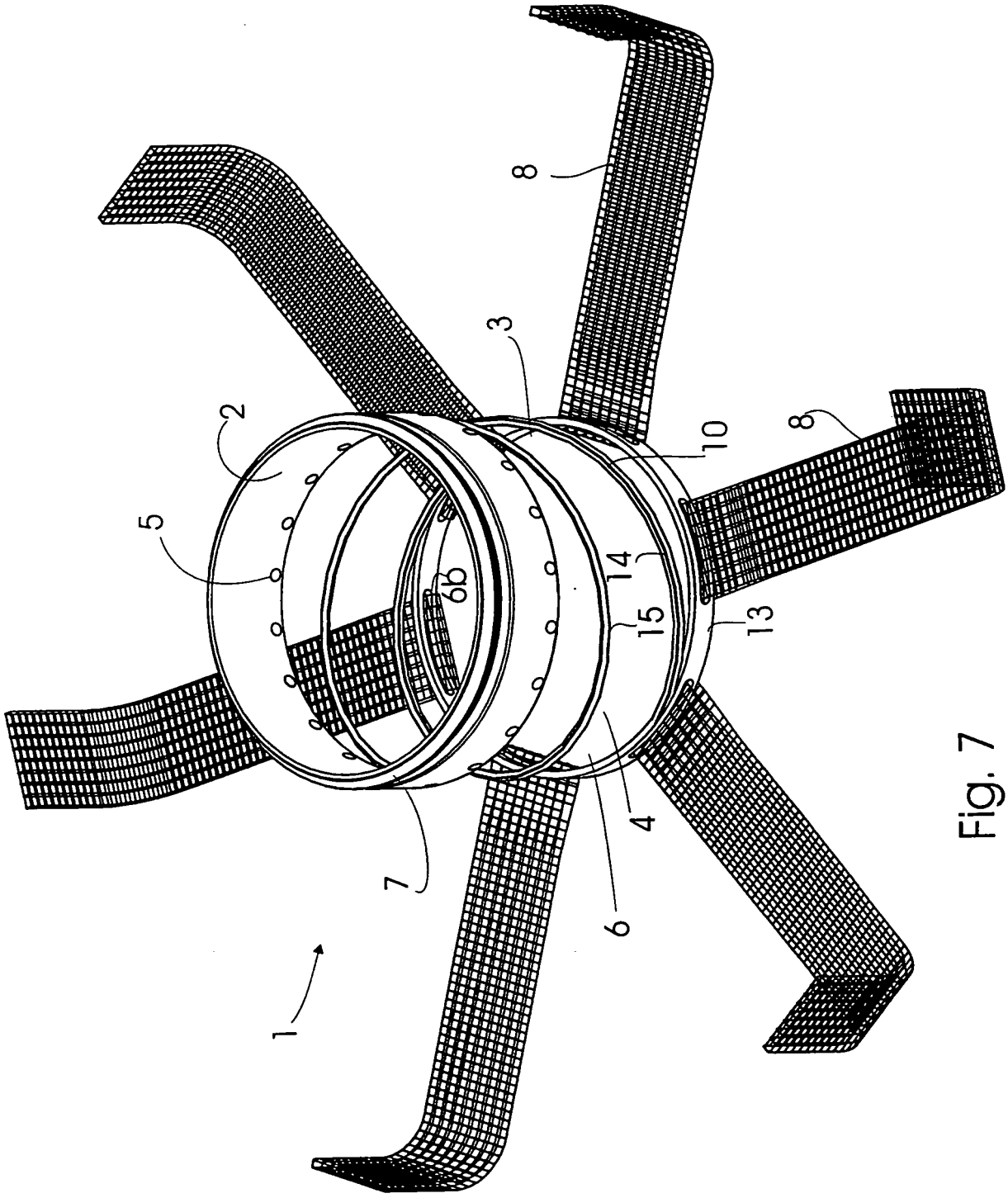

Fig. 7

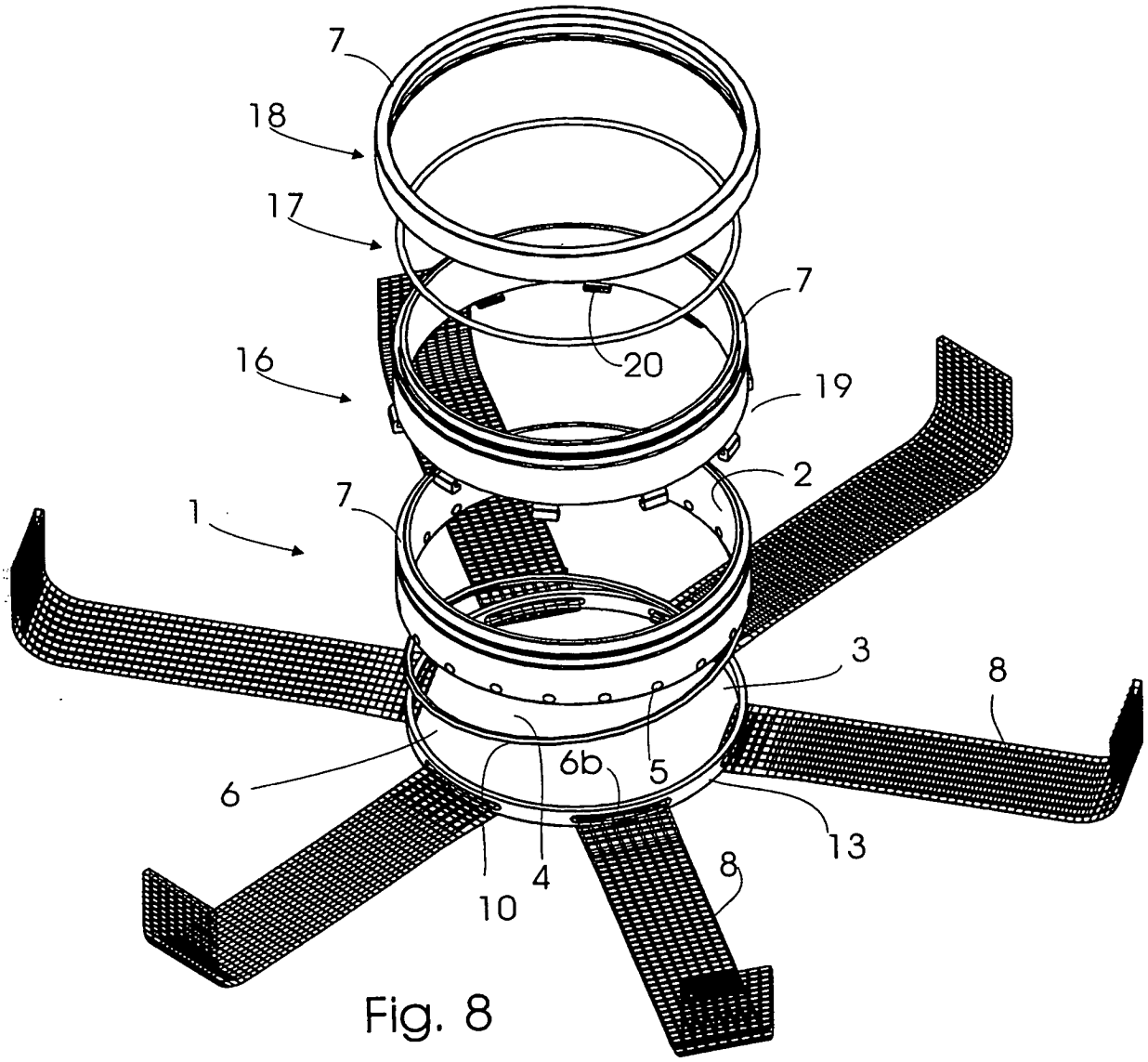

Fig. 8

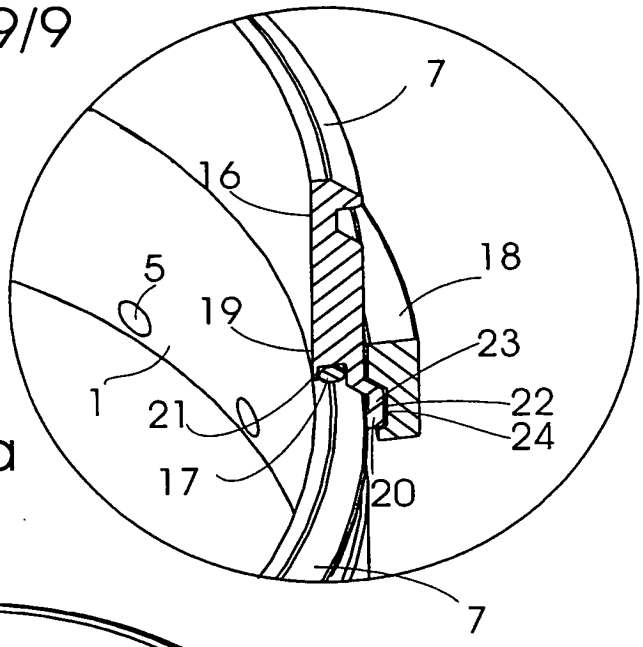

Fig. 9a

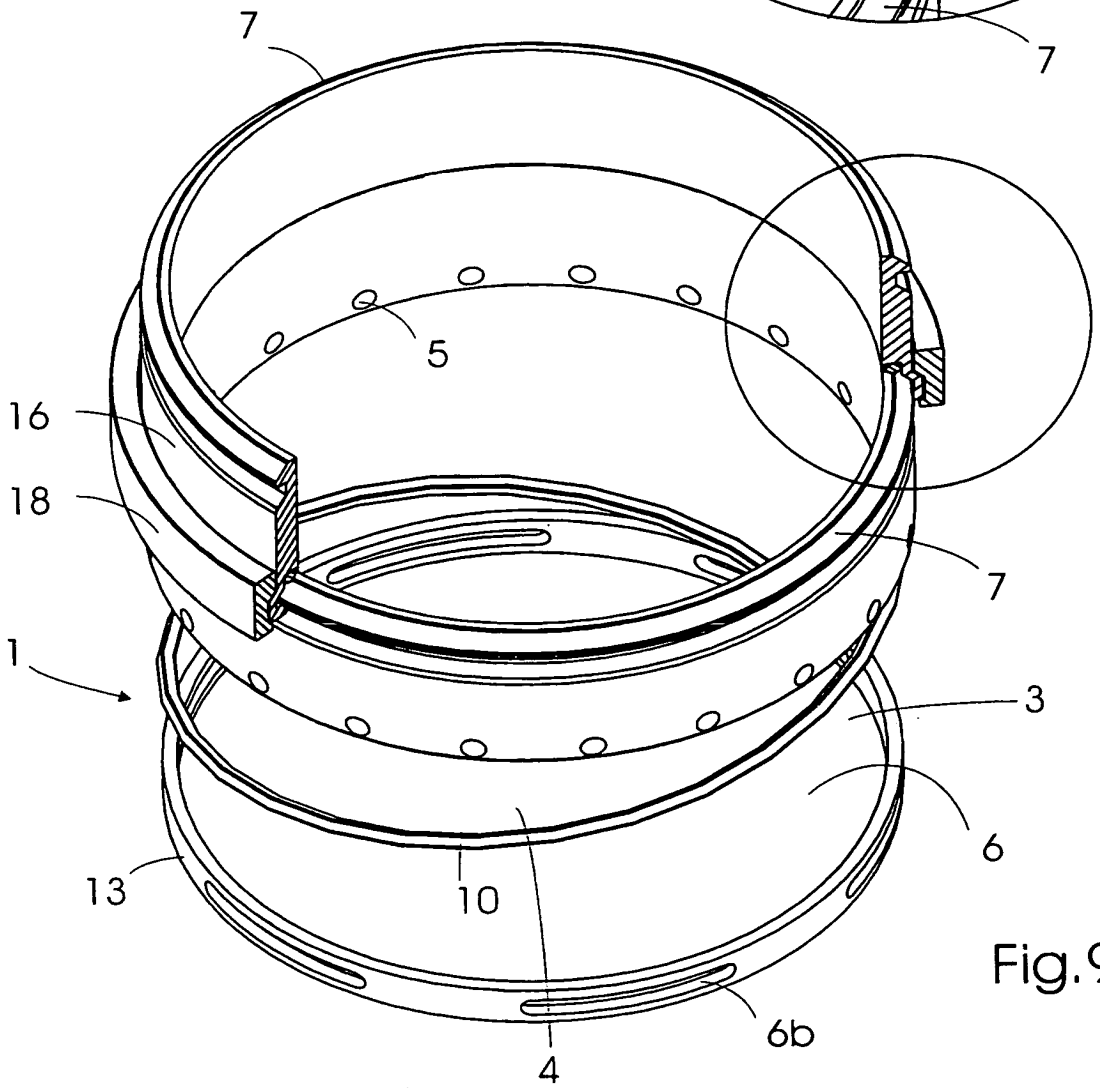

Fig.9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00394

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/02 // A61F 5/44
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4183357 A (DONALD J. BENTLEY ET AL), 15 January 1980 (15.01.80), column 3, line 52 - column 4, line 7, figures 1,6, abstract --	1,12
X	US 4217664 A (JOSEPH M. FASO), 19 August 1980 (19.08.80), column 7, line 13 - line 52, figures 1, 7 --	1-3,8-9,12
X	US 5085646 A (JAN A. SVENSON ET AL), 4 February 1992 (04.02.92), figure 4, claim 1 --	1

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 December 2000	13 -12- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander/Els Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00394

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5098398 A (DAN LUNDGREN), 24 March 1992 (24.03.92), column 1, line 55 - column 2, line 7, figures 1-2,6, abstract ---	1-3,12
A	WO 9858691 A1 (BIOTAP APS), 30 December 1998 (30.12.98), figure 2B --- --------	1,8-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/11/00

International application No.
PCT/DK 00/00394

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 4217664 A	19/08/80	NONE	
US 5085646 A	04/02/92	EP 0417089 A	20/03/91
		JP 3505285 T	21/11/91
		SE 463402 B,C	19/11/90
		SE 8800222 A	26/07/89
		WO 8910727 A	16/11/89
US 5098398 A	24/03/92	AT 83641 T	15/01/93
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		EP 0991437 A	12/04/00
		NO 996434 A	21/02/00
		US 6017355 A	25/01/00